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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,324	01/13/1999	YUKOH HIEI	760-262P	7108

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,324

Applicant(s)

HIEI ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

1. The request filed on June 19, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/229,324 is acceptable and a CPA has been established. An action on the CPA follows.

Status of the Claims

2. Claims 1-17 are pending. Claims 1-16 are examined in the instant application.
3. Newly submitted claim 17 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention of claim 17 has different starting materials, different steps, and different effects than the invention of claims 1-16.

Since applicant has received an action on the merits for the originally presented invention, this invention (claim 17) has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 17 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

4. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Information Disclosure Statement

5. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 10, is attached to the instant Office action.

Rejections Withdrawn

6. The 35 U.S.C. 112 first paragraph rejection of record are withdrawn in view of Applicant's traversal, response filed 4 April 2001, and in favor of new rejections set forth below.

Claim Rejections - 35 USC § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 1,

- Does “monocotyledon” mean a cell or a tissue or a plant?
- The first two steps appear to be reversed; the first step being “contacting a tissue”, and the second being “obtained by...”
- “obtained” is unclear because what is obtained is not specified.
- Is “explant” the same as “cultured tissue”?
- “contained” (line 9) is unclear: what is contained? The bacteria, the Agrobacterium or the super binary vector?
- “containing” is unclear: is it bacterium containing the super binary vector? Or the Agrobacterium containing the super binary vector?
- What has the “virulence region”? the Agrobacterium? the bacterium? or the super binary vector?
- “gene” is unclear because “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Suggested language is “a DNA of interest”. All subsequent recitations are also rejected.
- A clearer recitation dealing with some of these issues might include:
 - a super binary vector, wherein said super binary vector has
 - (a) the virulence region of Ti plasmid pTiBo542,
 - (b) left and right border sequences of T-DNA of a Ti or Ri plasmid belonging to the genus Agrobacterium, and

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(c) a desired DNA of interest, located between said left and right border sequences.--

Claims 1 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The final step of the method does not result in producing the desired product.

In claim 2, "said virulent region" lacks antecedent basis. Is this a typo?

Claim 9 is unclear because there are too many "ors".

- "transformation" lacks antecedent basis, as there is no transformation step in the claims.

In claim 10, what is a "normal" plant?

In claim 11, "several days" is indefinite. How many days are "several days"?

In claim 12, "is originated from" is indefinite because what of the original material is being retained is unspecified.

In claim 13, what "thereof" refers to is unclear. Is it the tissue, or the monocot?

- "contained" is unclear: what is contained? The bacteria, the Agrobacterium or the super binary vector?
- "containing" is unclear: is it bacterium containing the super binary vector? Or the Agrobacterium containing the super binary vector?

Claim 15, "plant" lacks antecedent basis.

The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document

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and are replete with grammatical and idiomatic errors. Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification lacks sufficient evidence that the claimed biological material (pTOK162) is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. If the claimed biological material were deposited under the provisions of the Budapest Treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest Treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent. Applicant's attention is directed to 37 C.F.R. §§ 1.801-1.809, M.P.E.P. §§ 2402-2411.05 and In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulations for Deposit of Biological Materials for Patent Purposes.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gould et al, Plant Physiol. (1991) 95, 426-434. Gould teaches *Agrobacterium* transformation of *Zea mays* shoot apices from germinating seedlings or embryos cultured for 1-3 days followed by inoculation with *Agrobacteria* (p 427, final 3 paragraphs, and p 428, 1st two paragraphs). Accordingly, Gould anticipates the claimed invention.

13. Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Graves et al, Plant Molecular Biology (1986) 7, 43-50. Graves teaches *Agrobacterium*

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transformation of Zea mays germinating seedlings cultured for 4 days followed by inoculation with Agrobacteria (p 44, 1st column last paragraph, continuing to 2nd column). Accordingly, Graves anticipates the claimed invention.

14. Claims 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al (US 6,215,051, effective filing date 4 November 1992). Yu teaches transformation of rice (Abstract, claims 1 and 8) by infecting precultured immature embryos (col 17, lines 12-15) with Agrobacterium two days later. Accordingly, Yu anticipates the claimed invention.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-11 and 13-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4, 7, and 9 of copending application 08/428,328. Although the conflicting claims are not identical,

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they are not patentably distinct from each other given the unclear recitation in instant claim 1 of "contacting ... during dedifferentiation... obtained by culturing an explant... for 1-6 days with a bacterium", instant claim 1 reads on contacting the explant after only one day of culture, insufficient for dedifferentiation.

The instant claims recite:

- one day cultured immature embryo (not yet dedifferentiated),
- virulence region from pTiBo542, and
- optionally, dedifferentiated culture 6 days after inoculation.

The copending claims recite:

- scutellum of immature embryo, not dedifferentiated (claim 1),
- virulence region from pTiBo542 (claim 9), and
- culture after inoculation to dedifferentiation (claim 7).

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. This is a provisional obviousness-type double patenting rejection.

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17. Claims 1-16 are rejected under the judicially created doctrine of double patenting over claims 1-3, 5-8, 10, 13-25 of U. S. Patent No. 5,591,616, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: "not less than 7 days " is an obvious variant of the "six days" encompassed by "1 to 6 days" of the instant application. Other plasmid and plasmid components instantly claimed are claimed in the patent.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

18. Applicant's assertions, in the response of 4 April 2001, to the contrary, are not probative. The specification did not evaluate dedifferentiation prior to 2 days of culture.

Remarks

19. Claims 1-12 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest *Agrobacterium* mediated transformation of monocot tissue cultured 1-6 days with a supervirulent vector.

20. No claim is allowed.

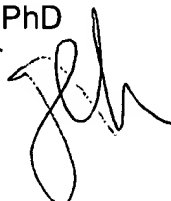
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21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
August 11, 2002



DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

